date on which the product involved re-
cieves permission for commercial mar-
keting or use. If within that 60-day pe-
riod the patent owner or its agent files 
an application for extension under 
§§1.740 and 1.741 including any addi-
tional information required under 35 
U.S.C. 156(d)(1) not contained in the 
application for interim extension, the 
patent shall be further extended in ac-
cordance with the provisions of 35 
U.S.C. 156.

[60 FR 25619, May 12, 1995] 

Subpart G—Biotechnology 
Invention Disclosures

DEPOSIT OF BIOLOGICAL MATERIAL

Source: 54 FR 34880, Aug. 22, 1989, unless otherwise noted.

§ 1.801 Biological material.

For the purposes of these regulations 
pertaining to the deposit of biological 
material for purposes of patents for in-
ventions under 35 U.S.C. 101, the term 
biological material shall include mate-
rial that is capable of self-replication 
either directly or indirectly. Rep-
resentative examples include bacteria, 
fungi including yeast, algae, protozoa, 
eukaryotic cells, cell lines, 
hybridomas, plasmids, viruses, plant 
tissue cells, lichens and seeds. Viruses, 
vectors, cell organelles and other non-
living material existing in and repro-
ducible from a living cell may be de-
posited by deposit of the host cell capa-
tible of reproducing the non-living mate-
rial.

§ 1.802 Need or opportunity to make a 
deposit.

(a) Where an invention is, or relies on, 
a biological material, the disclo-
sure may include reference to a deposit 
of such biological material.

(b) Biological material need not be deposited unless access to such mate-
rial is necessary for the satisfaction of 
the statutory requirements for patent-
ability under 35 U.S.C. 112. If a deposit 
is necessary, it shall be acceptable if made in accordance with these regulations. Biological material need not be deposited, inter alia, if it is known and readily available to the public or can be made or isolated without undue ex-
perimentation. Once deposited in a de-
pository complying with these regulations, a biological material will be con-
sidered to be readily available even though some requirement of law or reg-
ulation of the United States or of the 
country in which the depository insti-
tution is located permits access to the 
material only under conditions im-
posed for safety, public health or simi-
lar reasons.

(c) The reference to a biological ma-
terial in a specification disclosure or 
the actual deposit of such material by 
an applicant or patent owner does not 
create any presumption that such ma-
terial is necessary to satisfy 35 U.S.C. 
112 or that deposit in accordance with 
these regulations is or was required.

§ 1.803 Acceptable depository.

(a) A deposit shall be recognized for 
the purposes of these regulations if 
made in

(1) Any International Depositary Au-
thority (IDA) as established under the 
Budapest Treaty on the International 
Recognition of the Deposit of Micro-
organisms for the Purposes of Patent 
Procedure, or

(2) Any other depository recognized 
to be suitable by the Office. Suitability 
will be determined by the Director on 
the basis of the administrative and 
technical competence, and agreement 
of the depository to comply with the 
terms and conditions applicable to de-
posits for patent purposes. The Direc-
tor may seek the advice of impartial 
consultants on the suitability of a de-
pository. The depository must:

(i) Have a continuous existence;
(ii) Exist independent of the control 
of the depositor;
(iii) Possess the staff and facilities 
sufficient to examine the viability of a 
deposit and store the deposit in a man-
ner which ensures that it is kept viable 
and uncontaminated;
(iv) Provide for sufficient safety 
measures to minimize the risk of los-
ing biological material deposited with 
it;
(v) Be impartial and objective;
(vi) Furnish samples of the deposited 
material in an expeditious and proper 
manner; and
§ 1.804 Time of making an original deposit.

(a) Whenever a biological material is specifically identified in an application for patent as filed, an original deposit thereof may be made at any time before filing the application for patent or, subject to §1.809, during pendency of the application for patent.

(b) When the original deposit is made after the effective filing date of an application for patent, the applicant must promptly submit a statement from a person in a position to corroborate the fact, stating that the biological material which is deposited is a biological material specifically identified in the application as filed.


§ 1.805 Replacement or supplement of deposit.

(a) A depositor, after receiving notice during the pendency of an application for patent, application for reissue patent or reexamination proceeding, that the depository possessing a deposit either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, shall notify the Office in writing, in each application for patent or patent affected. In such a case, or where the Office otherwise learns, during the pendency of an application for patent, application for reissue patent or reexamination proceeding, that the depository possessing a deposit either cannot furnish samples thereof or can furnish samples thereof but the deposit has become contaminated or has lost its capability to function as described in the specification, the need for making a replacement or supplemental deposit will be governed by the same considerations governing the need for making an original deposit under the provisions set forth in §1.802(b). A replacement or supplemental deposit made during the pendency of an application for patent shall not be accepted unless it meets the requirements for making an original deposit under these regulations, including the requirement set forth under §1.804(b). A replacement or supplemental deposit made in connection with a patent, whether or not made during the pendency of an application for patent or reissuance proceeding, proceeding or both, shall not be accepted unless a certificate of correction under §1.323 is requested by the patent owner which meets the terms of paragraphs (b) and (c) of this section.