

(b) For community development purposes; and

(c) For administrative costs reasonably related to the above.

#### Clearance Requirements

##### § 183.11 What documents must the Tribe submit to request money from the Lease Fund?

To request a distribution of income from the Lease Fund, the Tribe must submit to us all of the following documents:

(a) A certified copy of a duly enacted resolution of the Tribal Council requesting a distribution from the Lease Fund;

(b) A pro forma budget for each identified economic development project and a program budget for each identified community development project, approved by the Tribal Council, showing precisely how the Tribe will spend the money;

(c) Supporting documentation for the budgets required by paragraph (b) of this section, and

(d) A certification stating that the Tribe will use the funds in accordance with budgets submitted under this section.

##### § 183.12 How long will it take to receive a decision?

Within 30 days of receiving the information required by § 183.11 we will approve your request if it complies with the Settlement Act and this part. If we disapprove your request we will do so in writing and will provide you with the reasons for disapproval.

##### § 183.13 What would cause the Secretary to disapprove a request?

We will only disapprove a request for distribution of income from the Lease Fund if the request does any of the following:

(a) Fails to provide the documents identified in § 183.5;

(b) Fails to provide reports required under §§ 183.15 and 183.16; or

(c) Includes a use requested or written budget that does not comply with a specific provision of the Settlement Act or this part.

#### Limitations

##### § 183.14 What limits are there on how the Tribe can spend funds?

(a) The Tribe must spend income distributed from the Lease Fund only in accordance with a written budget submitted under § 183.5.

(b) The Tribe must not spend the income from the Lease Fund to make per capita payments to members of the Tribe.

#### Subpart D—Reports

##### § 183.15 Must the Tribe submit any reports?

Yes. The Tribe must submit the following reports after receiving funds under this part:

(a) An Annual Report, that must be submitted no later than December 31 of each year; and

(b) A Financial Audit, that must be submitted no later than March 1 of each year.

##### § 183.16 What information must be included in the Tribe's annual report?

The Tribe's annual report must contain the following information:

(a) An accounting of the expenditures of funds distributed to the Tribe from the Trust Fund or the Lease Fund for the preceding 12 months;

(b) A description, in detail, of how the Tribe has used the funds distributed from the Trust Fund or the Lease Fund consistently with the requirements in the Settlement Act, this part, and the budget approved by the Tribal Council and the Secretary; and

(c) Sufficient documentation for us to determine that the Tribe has satisfied the requirements of paragraph (b) of this section.

#### Subpart E—Liability

##### § 183.17 If expenditures under this part lead to a claim or cause of action, who is liable?

The Tribe may be liable. The United States must not be liable for any claim or cause of action arising from the Tribe's use or expenditure of monies distributed from the Trust Fund or the Lease Fund.

##### § 183.18 Information Collection Requirements

The information collection requirements contained in this part do not meet the requirements of "ten or more persons" annually; therefore, the Office of Management and Budget does not need to clear the collection. You may direct comments concerning this information collection to the Bureau of Indian Affairs, Information Collection Control Officer, 1849 C Street, NW, Washington, DC 20240.

Dated: April 19, 2001.

**James H. McDivitt,**

*Deputy Assistant Secretary—Indian Affairs (Management).*

[FR Doc. 01-10250 Filed 4-26-01; 8:45 am]

BILLING CODE 4310-02-P

#### DEPARTMENT OF COMMERCE

##### United States Patent and Trademark Office

##### 37 CFR Part 1

[Docket No. 010208033-1033-01]

RIN 0651-AB33

##### Changes to the Time Period for Making Any Necessary Deposit of Biological Material

**AGENCY:** United States Patent and Trademark Office, Commerce.

**ACTION:** Final rule.

**SUMMARY:** In a rulemaking to implement the Patent Business Goals, the United States Patent and Trademark Office (Office) proposed a change to the time period within which a deposit of biological material (if needed) must be made. The Office held this proposed change in abeyance pending consideration of a study by the Comptroller General of the potential risks to the United States biotechnology industry relating to biological deposits as required by the American Inventors Protection Act of 1999. The Office is now, after consideration of this study, adopting a change to the time period within which a deposit of biological material (if needed) must be made and the depository information added to the specification.

**EFFECTIVE DATE:** May 29, 2001. This change is effective for any application in which a Notice of Allowability is mailed on or after May 29, 2001.

**FOR FURTHER INFORMATION CONTACT:** Robert W. Bahr, Karin L. Tyson, or Robert A. Clarke by telephone at (703) 308-6906, or by mail addressed to: Box Comments—Patents, Commissioner for Patents, Washington, DC 20231, or by facsimile to (703) 872-9411, marked to the attention of Robert W. Bahr.

**SUPPLEMENTARY INFORMATION:** In October of 1999, the Office proposed a number of changes to the rules of practice in title 37 of the Code of Federal Regulations to implement the Patent Business Goals. *See Changes to Implement the Patent Business Goals*, 64 FR 53771 (Oct. 4, 1999), 1228 *Off. Gaz. Pat. Office* 15 (Nov. 2, 1999) (Proposed Rule). Among the proposed changes was a proposal to amend § 1.809 to revise the time period within which a deposit of biological material (if needed) must be made and the depository information added to the specification. *See Changes to Implement the Patent Business Goals*, 64 FR 53814, 53842, 1228 *Off. Gaz. Pat. Office* 52, 78-79.

The American Inventors Protection Act of 1999 (Title IV of the Intellectual Property and Communications Omnibus Reform Act of 1999 (S. 1948) as introduced in the 106th Congress on November 17, 1999) was incorporated and enacted into law on November 29, 1999, by § 1000(a)(9), Division B, of Pub. L. 106–113, 113 Stat. 1501 (1999). Section 4805 of the American Inventors Protection Act of 1999 provides that the Comptroller General (in consultation with the Office) shall conduct a study and submit a report to Congress on the potential risks to the United States biotechnology industry relating to deposits of biological material in support of biotechnology patents, and that the Office shall consider the recommendations of such study in drafting regulations affecting deposits of biological material (including any modification of § 1.801 *et seq.*). Therefore, the Office held its proposed change to § 1.809 in abeyance pending the completion of the study. See *Changes to Implement the Patent Business Goals*, 65 FR 54603, 54651 (Sept. 8, 2000), 1238 *Off. Gaz. Pat. Office* 77, 118–19 (Sept. 19, 2000) (Final Rule).

The study required by section 4805 of the American Inventors Protection Act of 1999 was completed in October of 2000. See *Deposits of Biological Materials in Support of Certain Patent Applications*, GAO–01–49 (Oct. 2000). This report may be obtained: (1) By mail addressed to U.S. General Accounting Office, P.O. Box 37050, Washington, DC 20013; (2) in person by visiting Room 1100, 700 4th Street, NW. (Corner of 4th Street and G Street, NW.), U.S. General Accounting Office, Washington, DC, (3) by telephone at (202) 512–6000, facsimile at (202) 512–6061, or TDD (202) 512–2537; or (4) via the General Accounting Office's Internet Web site at <http://www.gao.gov>. The study did not contain any recommendations related to the Office's proposal to amend § 1.809 to revise the time period within which a deposit of biological material (if needed) must be made. Therefore, the Office is now revising § 1.809 based upon its October 1999 proposal.

#### Discussion of Specific Rules

Title 37 of the Code of Federal Regulations, Part 1, is amended as follows:

**Section 1.136:** Section 1.136(c) is amended to add the period for making a deposit set under § 1.809(c) to the time periods that are not extendable under § 1.136 if an applicant is notified in a "Notice of Allowability" that an application is otherwise in condition for allowance, or in an Office action having

a mail date on or after the mail date of the "Notice of Allowability."

**Section 1.809:** Section 1.809(b) is amended to change "respond" to "reply" (see § 1.111), and to eliminate the language relating to payment of the issue fee.

Section 1.809(c) is amended to: (1) Provide that if an application for patent is otherwise in condition for allowance except for a needed deposit and the Office has received a written assurance that an acceptable deposit will be made, applicant will be notified and given a period of time within which the deposit must be made in order to avoid abandonment; (2) provide that this time period is not extendable under § 1.136(a) or (b) if set forth in a "Notice of Allowability" or in an Office action having a mail date on or after the mail date of a "Notice of Allowability" (see § 1.136(c)); and (3) eliminate the language stating that failure to make a needed deposit will result in abandonment for failure to prosecute, because abandonment for failure to prosecute occurs by operation of law when an applicant fails to timely comply with such a requirement (see 35 U.S.C. 133). If an application for patent is otherwise in condition for allowance except for a needed deposit, the Office will notify applicant in the "Notice of Allowability" that a deposit is required, and the "Notice of Allowability" will set a three-month (non-extendable) period within which the deposit must be made in order to avoid abandonment of the application.

Section 1.809(e) is added to remind applicants that the amendment required by § 1.809(d) must be filed before or with the payment of the issue fee. The rules of practice no longer permit amendments to be filed after payment of the issue fee. See § 1.312. Therefore, applicants need to make any necessary deposit of biological material well prior to payment of the issue fee such that the accession number is received with sufficient time remaining to amend the specification as required by § 1.809(d) on or before the date the issue fee is paid. If the amendment required by § 1.809(d) is not filed before or with the payment of the issue fee, applicant will need to submit the amendment with a petition under § 1.183 to waive the requirement of § 1.312 that any amendment after the mailing of a notice of allowance be filed before or with the payment of the issue fee so as to permit entry of the amendment required by § 1.809(d).

Finally, applicants are encouraged to make the deposit when filing the patent application in order to avoid possible loss of the U.S. filing date in other

countries. See *Manual of Patent Examining Procedure* § 2406.03 (July 1998).

#### Classification

**Administrative Procedure Act:** This final rule only changes the time period within which a deposit under § 1.801 *et seq.* must be filed (if needed). Therefore, this change concerns only rules of Office procedure, and prior notice and an opportunity for public comment for this change is not required pursuant to 5 U.S.C. 553(b)(A), or any other law. However, a notice of proposed rulemaking was published in the **Federal Register** and the Official Gazette, and no comments on the proposed change were received. See *Changes to Implement the Patent Business Goals*, 64 FR 53771 (Oct. 4, 1999), 1228 *Off. Gaz. Pat. Office* 15 (Nov. 2, 1999) (Proposed Rule).

**Regulatory Flexibility Act:** The Assistant General Counsel for Legislation and Regulation of the Department of Commerce certified to the Chief Counsel for Advocacy of the Small Business Administration that this rule will not have a significant economic impact on a substantial number of small entities. No comments were received regarding the economic impact of this rule. As a result, no regulatory flexibility analysis was prepared.

**Executive Order 13132:** This final rule does not contain policies with federalism implications sufficient to warrant preparation of a Federalism Assessment under Executive Order 13132 (August 4, 1999).

**Executive Order 12866:** This final rule has been determined to be not significant for purposes of Executive Order 12866 (September 30, 1993).

**Paperwork Reduction Act:** This final rule involves information collection requirements which are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*). The collection of information involved in this final rule has been reviewed and previously approved by OMB under the following control number 0651–0022. The United States Patent and Trademark Office is not resubmitting an information collection package to OMB for its review and approval because the changes in this final rule do not affect the information collection requirements associated with the information collection under OMB control number 0651–0022.

The title, description and respondent description of this information collection is shown below with an estimate of the annual reporting

burdens. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information. The principal impact of the changes in this final rule is a change in the time period for filing a deposit under § 1.801 *et seq.* (if needed).

OMB Number: 0651-0022.

Title: Deposit of Biological Materials for Patent Purposes.

Form Numbers: None.

Type of Review: Routine submission.

Affected Public: Individuals or Households, State or Local Governments, Farms, Business or Other For-Profit, Federal Agencies or Employees, Not-for-Profit Institutions, Small Businesses or Organizations.

Estimated Number of Respondents: 3,300.

Estimated Time Per Response: 1.0 hour.

Estimated Total Annual Burden Hours: 3,300 hours.

Needs and Uses: Information on depositing of biological materials in depositories is required for (1) Office determination of compliance with the patent statute where the invention sought to be patented relies on biological material subject to deposit requirement, which includes notifying interested members of the public where to obtain samples of deposits, and (2) depositories desiring to be recognized as suitable by the Office.

Comments are invited on: (1) Whether the collection of information is necessary for proper performance of the functions of the agency; (2) the accuracy of the agency's estimate of the burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information to respondents.

Interested persons are requested to send comments regarding these information collections, including suggestions for reducing this burden, to Robert J. Spar, Director, Office of Patent Legal Administration, United States Patent and Trademark Office, Washington, DC 20231, or to the Office of Information and Regulatory Affairs, OMB, 725 17th Street, NW, Washington, DC 20503, (Attn: PTO Desk Officer).

Notwithstanding any other provision of law, no person is required to respond to nor shall a person be subject to a penalty for failure to comply with a collection of information subject to the requirements of the Paperwork Reduction Act unless that collection of information displays a currently valid OMB control number.

#### List of Subjects in 37 CFR Part 1

Administrative practice and procedure, Courts, Freedom of Information, Inventions and patents, Reporting and record keeping requirements, Small Businesses.

For the reasons set forth in the preamble, 37 CFR Part 1 is amended as follows:

#### PART 1—RULES OF PRACTICE IN PATENT CASES

1. The authority citation for 37 CFR part 1 continues to read as follows:

Authority: 35 U.S.C. 2(b)(2).

Section 1.136 is amended by revising paragraph (c) to read as follows:

##### § 1.136 Extensions of time.

(c) If an applicant is notified in a "Notice of Allowability" that an application is otherwise in condition for allowance, the following time periods are not extendable if set in the "Notice of Allowability" or in an Office action having a mail date on or after the mail date of the "Notice of Allowability":

(1) The period for submitting an oath or declaration in compliance with § 1.63;

(2) The period for submitting formal drawings set under § 1.85(c); and

(3) The period for making a deposit set under § 1.809(c).

Section 1.809 is amended by revising paragraphs (b) and (c) and adding paragraph (e) to read as follows:

##### § 1.809 Examination procedures.

(b) The applicant for patent or patent owner shall reply to a rejection under paragraph (a) of this section by—

(1) In the case of an applicant for patent, either making an acceptable original, replacement, or supplemental deposit, or assuring the Office in writing that an acceptable deposit will be made; or, in the case of a patent owner, requesting a certificate of correction of the patent which meets the terms of paragraphs (b) and (c) of § 1.805, or

(2) Arguing why a deposit is not needed under the circumstances of the application or patent considered and/or why a deposit actually made should be accepted. Other replies to the examiner's action shall be considered nonresponsive. The rejection will be repeated until either paragraph (b)(1) of this section is satisfied or the examiner is convinced that a deposit is not needed.

(c) If an application for patent is otherwise in condition for allowance except for a needed deposit and the Office has received a written assurance

that an acceptable deposit will be made, applicant will be notified and given a period of time within which the deposit must be made in order to avoid abandonment. This time period is not extendable under § 1.136(a) or (b) if set forth in a "Notice of Allowability" or in an Office action having a mail date on or after the mail date of a "Notice of Allowability" (see § 1.136(c)).

(e) Any amendment required by paragraphs (d)(1), (d)(2) or (d)(4) of this section must be filed before or with the payment of the issue fee (see § 1.312).

Dated: April 18, 2001.

Nicholas P. Godici,

Acting Under Secretary of Commerce for Intellectual Property and Director of the United States Patent and Trademark Office.

[FR Doc. 01-10188 Filed 4-26-01; 8:45 am]

BILLING CODE 3510-16-U

#### ENVIRONMENTAL PROTECTION AGENCY

#### 40 CFR Part 62

[Docket # RI040-7167a; FRL-6971-1]

#### Approval and Promulgation of State Plans for Designated Facilities and Pollutants: Rhode Island; Plan for Controlling Emissions From Existing Hospital/Medical/Infectious Waste Incinerators

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

**SUMMARY:** The Environmental Protection Agency (EPA) approves the Sections 111(d)/129 State Plan submitted by the Rhode Island Department of Environmental Management (RIDEM) on August 23, 2000. This State Plan is for implementing and enforcing provisions at least as protective as the Emissions Guidelines (EGs) applicable to existing Hospital/Medical/Infectious Waste Incinerators (HMIWIs) for which construction commenced on or before June 20, 1996.

**DATES:** This direct final rule is effective on June 26, 2001 without further notice unless EPA receives significant adverse comment by May 29, 2001. If adverse comment is received EPA will publish a timely withdrawal in the **Federal Register** informing the public that this rule will not take effect.

**ADDRESSES:** You should address your written comments to: Mr. Steven Rapp, Manager, Air Permits Unit, Office of Ecosystem Protection, U.S. EPA-New England, Region 1, One Congress Street,