your final report, unless we specify otherwise.

§ 822.34 What must I do with the records if the sponsor of the plan or an investigator in the plan changes?

If the sponsor of the plan or an investigator in the plan changes, you must ensure that all records related to the postmarket surveillance have been transferred to the new sponsor or investigator and notify us within 10 working days of the effective date of the change. You must provide the name, address, and telephone number of the new sponsor or investigator, certify that all records have been transferred, and provide the date of transfer.

§ 822.35 Can you inspect my manufacturing site or other sites involved in my postmarket surveillance plan?

We can review your postmarket surveillance programs during regularly scheduled inspections, inspections initiated to investigate recalls or other similar actions, and inspections initiated specifically to review your postmarket surveillance plan. We may also inspect any other person or site involved in your postmarket surveillance, such as investigators or contractors. Any person authorized to grant access to a facility must permit authorized FDA employees to enter and inspect any facility where the device is held or where records regarding postmarket surveillance are held.

§ 822.36 Can you inspect and copy the records related to my postmarket surveillance plan?

We may, at a reasonable time and in a reasonable manner, inspect and copy any records pertaining to the conduct of postmarket surveillance that are required to be kept by this regulation. You must be able to produce records and information required by this regulation that are in the possession of others under contract with you to conduct the postmarket surveillance. Those who have signed agreements or are under contract with you must also produce the records and information upon our request. This information must be produced within 72 hours of the initiation of the inspection. We generally will redact information pertaining to individual subjects prior to copying those records, unless there are extenuating circumstances.

§ 822.37 Under what circumstances would you inspect records identifying subjects?

We can inspect and copy records identifying subjects under the same circumstances that we can inspect any records relating to postmarket surveillance. We are likely to be interested in such records if we have reason to believe that required reports have not been submitted, or are incomplete, inaccurate, false, or misleading.

§ 822.38 What reports must I submit to you?

You must submit interim and final reports as specified in your approved postmarket surveillance plan. In addition, we may ask you to submit additional information when we believe that the information is necessary for the protection of the public health and implementation of the act. We will also state the reason or purpose for the request and how we will use the information.

Dated: December 26, 2001.

Margaret M. Dotzel,

Associate Commissioner for Policy.

[FR Doc. 02–14100 Filed 6–5–02; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF STATE

22 CFR Parts 41 and 42

[Public Notice 4028]

Documentation of Immigrants and Nonimmigrants Under the Immigration and Nationality Act, as Amended—Visa Fees: Interim Rule With Request for Comments

AGENCY: Department of State.

ACTION: Interim rule with request for comments.

SUMMARY: This rule reflects and conforms visa regulations to the changes made in a final rule amending the Schedule of Consular Services Fees published on Thursday, May 16, 2002. The latter rule waives all nonimmigrant visa fees for U. S. Government foreign national employees who are travelling to the United States on official business. It also provides for merging the processing and issuance fees associated with immigrant visas. Each of those changes necessitates the revision of related visa regulations. Finally, this rule eliminates a subsection relating to the validity of visas issued to certain residents of Hong Kong, because the law underlying that provision expired on January 1, 2002.

DATES: Written comments may be submitted on or before July 8, 2002.

ADDRESSES: Written comments may be submitted, in duplicate, to the Legislation and Regulations Division, Visa Services, Department of State, Washington, DC 20520–0106 or by e-mail to *visaregs@state.gov.*

FOR FURTHER INFORMATION CONTACT: Elizabeth J. Harper, Legislation and Regulations Division, Visa Services, Department of State, Washington, D.C. 20520–0106, (202) 663–1221, e-mail *harperb@state.gov,* or fax at (202) 663–3898 with respect to the legal sufficiency of this rule or similar matters. For enquiries about the effect of this rule on individual cases, contact the Visa Office by e-mail at *www.usvisa.state.gov.* See reference to Susan Abeyta below, regarding comments on the changes in the Schedule of Fees.

SUPPLEMENTARY INFORMATION: A current regulation, at 22 CFR 41.107(c), lists the two classes of aliens who are exempt from the payment of nonimmigrant visa fees. This rule adds foreign employees of the U.S. Government who will travel to the United States on official business to that list.

With respect to immigrant visas, 22 CFR 42.71(b) currently identifies two levels of activity for which fees are assessed. The first is for the processing of an application for an immigrant visa and the second is for the issuance of such a visa. It also sets forth different time frames for the collection of such individual fees. As the Department is combining these fees into a single fee covering all processing functions, editorial changes to 42.71 have become necessary. The timing of the payment of these fees and the basis for the refund of the single fee have been appropriately modified to accord with having one fee rather than separate fees for separate services.

Why Are These Changes Being Made?

The changes in this interim rule are necessary, as stated above, because the Schedule of Consular Services Fees was recently amended in a final rule published May 16, 2002 (Public Notice 4016; 67 FR 34831).

Why Was the Fee Schedule Changed?

A cost study underlies the changes in the proposed new Schedule of Consular Fees, which includes some modest increases in some visa fees. The considerations taken into account are set forth fully in the rule pertaining to the new Schedule. Any questions regarding the changes in the fee schedule should be directed to Susan Abeyta, Office of the Executive Director, Bureau of Consular Affairs, telefax: (202) 663–2499; e-mail: fees@state.gov as noted in that proposed rule.

Why Is There a Waiver of Fees for Some Nonimmigrants and Not Others?

The Congress in a public law enacted one of the current waivers of fees and

another results from international comity. The latest addition to the list, made in this rule, is for non-citizen employees of the United States Government, who are employed abroad but coming to the United States on official business in connection with that employment. We believe such travel to be primarily in the interest of the U.S. Government, so that the issuance of the visa is not primarily a benefit to the traveler for which a fee would be charged.

Are There Any Other Changes in This Regulation?

Yes. We are making editorial amendments in the several places where references to ''application and issuance fees'' appear in other sections of part 42, to conform with the language changes discussed above. We are also deleting a subsection of 22 CFR 42.72 relating to immigrants from Hong Kong because the underlying statute expired on January 1, 2002.

Regulatory Analysis and Notices

Administrative Procedure Act

The Department is publishing this rule as a proposed rule, with a 30-day provision for public comments, to accord with the proposed rule it is complementing.

Regulatory Flexibility Act

Pursuant to § 605 of the Regulatory Flexibility Act, the Department has assessed the potential impact of this rule, and the Assistant Secretary for Consular Affairs hereby certifies that it is not expected to have a significant economic impact on a substantial number of small entities.

Unfunded Mandates Reform Act of 1995

This rule will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100 million in any year and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996

This rule is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Act of 1996. This rule will not result in an annual effect on the economy of $100 million or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

Executive Order 12866

The Department of State does not consider this rule to be a ''significant regulatory action'' under Executive Order 12866, section 3(f), Regulatory Planning and Review. In addition, the Department is exempt from Executive Order 12866 except to the extent that it is promulgating regulations in conjunction with a domestic agency that are significant regulatory actions. The Department has nevertheless reviewed the regulation to ensure its consistency with the regulatory philosophy and principles set forth in that Executive Order.

Executive Order 13132

This regulation will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with section 6 of Executive Order 13132, it is determined that this rule does not have sufficient federalism implications to require consultations or warrant the preparation of a federalism summary impact statement.

Paperwork Reduction Act

This rule does not impose any new reporting or record-keeping requirements subject to the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Parts 41 and 42

Aliens, Fees, Immigrants, Nonimmigrants, Passports and visas.

Accordingly, the Department of State amends 22 CFR Chapter I as set forth below:

PART 41—[AMENDED]

1. The authority citation for part 41 continues to read as follows:

Authority: 8 U.S.C. 1104; Pub. L. 105–277, 112 Stat. 2681 *et seq.*

2. Add to § 41.107(c) a new paragraph (c)(3) to read as follows:

§ 41.107 Visa Fees.

* * * * *

(c) *Certain aliens exempted from fees.*

* * * * *

(3) Foreign national employees of the U. S. Government who are travelling to the United States on official business in connection with that employment.

* * * * *

PART 42—[AMENDED]

3. The authority citation for part 42 continues to read as follows:

Authority: 8 U.S.C. 1104.

4. Revise § 42.33(h)(2) to read as follows:

§ 42.33 Diversity Immigrants.

* * * * *

(h) *Further processing.*

* * * * *

(2) Names of visa recipients shall not be maintained in connection with this information and the information shall be compiled and maintained in such form that the identity of visa recipients cannot be determined therefrom.

(i) *Diversity Visa Lottery Surcharge.* In addition to collecting the immigrant visa application processing fee, as provided in § 42.71(b) of this part, the consular officer shall also collect from each applicant for a visa under the Diversity Immigrant Visa Program such fee for the processing of the diversity lottery as the Secretary of State prescribes.

(ii) [Reserved]

5. Revise § 42.71 to read as follows:

§ 42.71 Authority to issue visas; visa fees.

(a) *Authority to issue visas.* Consular officers may issue immigrant visas at designated consular offices abroad pursuant to the authority contained in INA 101(a)(16), 221(a), and 224. (Consular offices designated to issue immigrant visas are listed periodically in Visa Office Bulletins published at www.travel.state.gov by the Department of State.) A consular officer assigned to duty in the territory of a country against which the sanctions provided in INA 243(d) have been invoked must not issue an immigrant visa to an alien who is a national, citizen, subject, or resident of that country, unless the officer has been informed that the sanction has been waived by INS in the case of an individual alien or a specified class of aliens.

(b) *Immigrant visa fees.* The Secretary of State prescribes a fee for the processing of immigrant visa applications. An individual registered for immigrant visa processing at a post designated for this purpose by the Deputy Assistant Secretary for Visa Services must pay the processing fee upon being notified that a visa is expected to become available in the near future and being requested to obtain the supporting documentation needed to apply formally for a visa. A fee collected for the processing of an immigrant visa application is refundable only if the principal officer of a post or the officer

in charge of a consular section determines that the application was not adjudicated as a result of action by the U. S. Government over which the alien had no control and for which the alien was not responsible, that precluded the applicant from benefiting from the processing.

§ 42.72 [Amended]

6. Amend § 42.72 by removing and reserving paragraph (c).

§ 42.74 [Amended]

7. Amend § 42.74 by:

a. In paragraph (a)(2)(i), (b)(iv), and (c), removing ''statutory'', removing ''and issuance'' and adding in its place ''processing'', and adding ''prescribed in the Schedule of Fees'' after ''fees''; and

b. In paragraph (b)(1)(v) add an ''s'' to ''ascertain''.

Dated: April 19, 2002.

Mary A. Ryan,

Assistant Secretary for Consular Affairs, Department of State.

[FR Doc. 02–13001 Filed 6–5–02; 8:45 am]

BILLING CODE 4710–06–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[PA 182–4196a; FRL–7224–8]

Approval and Promulgation of Air Quality Implementation Plans; Pennsylvania; Motor Vehicle Inspection and Maintenance Program—Request for Delay in the Incorporation of On-Board Diagnostics Testing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is taking direct final action to approve a revision to the Pennsylvania State Implementation Plan (SIP). Pennsylvania has requested a one-year extension of the Federal deadline to incorporate electronic checks of on-board diagnostic (OBD) computer systems of 1996-and-newer vehicles into the Commonwealth's motor vehicle emissions inspection and maintenance (I/M) program. EPA's rules governing I/M programs required states to add OBD checks to their I/M programs by January 1, 2002. However, EPA's same rule provides states the option to submit a request for delay of this deadline by up to one additional year, provided each state making such a request demonstrates to EPA that such a delay was necessary. Pennsylvania has requested the maximum delay provided for by EPA's regulations (i.e., until January 1, 2003) in commencing OBD checks as part of its I/M program. EPA has reviewed Pennsylvania's request, and is proposing through this action to grant Pennsylvania's request for a one year extension of the OBD testing deadline in accordance with the requirements of the Clean Air Act.

DATES: This rule is effective on August 5, 2002, without further notice, unless EPA receives adverse written comment by July 8, 2002. If EPA receives such comments, it will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: Written comments should be mailed to David L. Arnold, Chief, Air Quality Planning and Information Services Branch, Mail code 3AP21, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of the documents relevant to this action are available for public inspection during normal business hours at the Air Protection Division, U.S. Environmental Protection Agency, Region III, 1650 Arch Street, Philadelphia, Pennsylvania 19103. Copies of these relevant documents are also available from the Pennsylvania Department of Environmental Protection, Bureau of Air Quality, P.O. Box 8468, 400 Market Street, Harrisburg, Pennsylvania 17105.

FOR FURTHER INFORMATION CONTACT: Brian Rehn, (215) 814–2176, or by e-mail at *rehn.brian@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

On April 5, 2001, EPA's revised I/M program requirements rule was published in the **Federal Register** (Amendments to Vehicle Inspection and Maintenance Program Requirements Incorporating the Onboard Diagnostics Check; Final Rule (66 FR 18156)). The revised I/M requirements rule requires that electronic checks of the on-board diagnostics system of applicable 1996-and-newer motor vehicles (OBD) be conducted as part of states' motor vehicle I/M programs. This revised I/M requirements rule applies only to those areas required to implement an I/M program under the Clean Air Act of 1990. This rule establishes a deadline of January 1, 2002 for states to begin performing OBD checks on 1996-and-newer model OBD-equipped vehicles, and to require repairs to be performed on those vehicles with malfunctions identified by the OBD check. However, the revised I/M rule also provides several options to states to delay implementation of OBD testing, under certain circumstances, beyond the prescribed January 1, 2002 deadline. One such option provides for a one-time, 12-month extension of the deadline for states to begin conducting mandatory OBD checks (to as late as January 1, 2003) provided the state making the request can show just cause to EPA for a delay and that the revised implementation date represents ''the best the state can reasonably do''.

EPA's final rule identifies factors that may serve as a possible justification for states considering making a request to EPA to delay implementation of OBD I/M program checks beyond the January 2002 deadline. Potential factors justifying such a delay request that are listed in EPA's rule include: contractual impediments, hardware or software deficiencies, data management software deficiencies, the need for additional training for the testing and repair industries, and the need for public education or outreach.

Pennsylvania has submitted a SIP revision to formally request an extension of the OBD I/M test deadline, per EPA's I/M requirement rule. Pennsylvania's SIP revision lists many of the same factors that are listed in EPA's I/M rule in order to justify the Commonwealth's request for extension of the OBD testing deadline in Pennsylvania.

Summary of SIP Revision

On December 14, 2001, Pennsylvania submitted a formal revision to its State Implementation Plan (SIP), which constitutes a request to delay the addition of on-board diagnostic system checks of 1996-and-newer vehicles to the Commonwealth's adopted and SIP-approved I/M program.

Pennsylvania's SIP revision to request a delay in adding OBD testing to its I/M program lists several factors that effect the Commonwealth's ability to conduct OBD testing at this time. The Commonwealth's justification for its request of a one-year delay includes the following factors:

(1) Hardware and software deficiencies associated with the OBD testing equipment and its ability to communicate with Pennsylvania's Vehicle Inspection Information Database (VIID), as well as the commercial availability of equipment meeting the Commonwealth's specifications and requirements,

(2) Software deficiencies related to Pennsylvania's VIID, pertaining to communications between testing stations and the program oversight contractor and the VIID,