Supporting Statement

Import Permit Applications (42 CFR 71.54)

(OMB Control No. 0920-0199)

Revision

Centers for Disease Control and Prevention

Center for Preparedness and Response

Division of Select Agents and Toxins

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- The goal of this information collection is to support Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) and fulfill the requirements promulgated by the Department of Health and Human Services under 42 CFR 71.54.
- The intended use of the data is to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the United States or possessions, or from one State or possession into any other State or possession.
- The method used to collect data/information is an electronic data collection system managed by the Centers for Disease Control and Prevention's Import Permit Program. Electronic forms are posted on the IPP website at https://www.cdc.gov/cpr/ipp/applications/index.htm.
- The subpopulation to be studied are those academic institutions and biomedical centers, commercial manufacturing facilities, federal, state, and local laboratories, including clinical and diagnostic laboratories, research facilities, exhibition facilities, and educational facilities to request a permit for the importation, and any subsequent distribution after importation, of biological agents, infectious substances, or vectors of human disease. The subpopulation are those facilities that will bury/cremate the imported cadaver and educational facilities that request a permit for the importation and subsequent transfers throughout the U.S. of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease.
- This collection of information does not employ statistical methods. The data collection is mandated by 42 CFR 71.54.

A. Justification

In this information collection request, CDC requests OMB approval for minor changes to one form, the Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States. CDC also describes two sources of burden reduction: 1) efficiencies due to implementation of a new electronic information collection system, and (2) adjustments to the estimated number of responses.

1. Circumstances Making the Collection of Information Necessary

Section 361 of the Public Health Service Act (42 U.S.C. 264) (Attachment 1a), as amended, authorizes that the Secretary of Health and Human Services (HHS) make and enforce such regulations as are necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession. Part 71 of Title 42, Code of Federal Regulations (Foreign Quarantine) sets forth provisions to prevent the introduction, transmission, and spread of communicable disease from foreign countries into the United States. Subpart F – Importations - contains provisions for the importation of infectious biological agents, infectious substances, and

vectors (42 CFR 71.54); requiring persons that import these materials to obtain a permit issued by the CDC. The Centers for Disease Control and Prevention's Import Permit Program (IPP) regulates the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States. Prior to issuing an import permit, IPP reviews all applications to ensure that entities have appropriate safety measures in place for working safely with these imported materials.

2. Purpose and Use of Information Collection

This information will assist with meeting the goals of the Section 361 of the Public Health Service (PHS) Act (42 U.S.C. 264) (Attachment 1a) in preventing the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

The *Permit to Import Biological Agents and Vectors of Human Disease into the United States* collects required information from laboratory facilities, such as those operated by academic institutions and biomedical centers; commercial manufacturing facilities; federal, state, and local laboratories, including clinical and diagnostic laboratories; research facilities; exhibition facilities and educational facilities to request a permit for the importation, and any subsequent distribution after importation, of biological agents, infectious substances, or vectors of human disease. This form currently requests applicant and sender contact information; a description of material for importation; facility isolation and containment information; and personnel qualifications. CDC plans to revise this application to:

- Remove question 10 "Will the permittee be the courier of the imported biological agent?" from Section A since it is the same question found in section C, question 1.
- Add example to section F, question 2 for clarity to read, "Protective Clothing (e.g., laboratory coat)."

The *Application for Permit to Import or Transport Live Bats* collects required information from laboratory facilities, such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation, and any subsequent distribution after importation, of live bats. This form currently requests the applicant and sender contact information; a description and intended use of bats to be imported; and facility isolation and containment information. CDC does not plan to revise this application.

The *Application for Permit to Import Infectious Human Remains into the United States* collects required information from facilities that will bury/cremate an imported cadaver and by educational facilities that request a permit for the importation (and subsequent transfers throughout the U.S.) of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease. This form requests applicant and sender contact information; identification of the facility processing human remains; cause of death; biosafety and containment information; and final destination(s) of imported infectious human remains. CDC does not plan to revise this application.

3. Use of Improved Technology and Burden Reduction

The electronic forms are available at the CDC's Import Permit Program website (https://www.cdc.gov/cpr/ipp/applications/index.htm) through the eIPP system. The eIPP is a secure, user-friendly, electronic information system through which those seeking import permits apply for the permit.

4. Efforts to Identify Duplication and Use of Similar Information

42 CFR 71.54 specifies that the importation permit is granted by CDC. No other component of HHS is involved in these procedures. The only way to obtain the necessary information is from the applicant.

5. Impact on Small Businesses or Other Small Entities

Collection of information is not targeted to small businesses or entities, but may involve some small businesses or other small entities. Burden has been limited to providing minimal information on forms, verifying information by telephone, and mailing information to the appropriate parties. CDC has made every effort to ensure that the information collection is the minimal amount necessary to meet the requirements of the law and places a minimal burden on all parties involved.

6. Consequences of Collecting the Information Less Frequently

There are legal obstacles to reducing the burden by collecting this information less frequently. The purpose of this information collection is to meet mandated regulatory requirements. If this information were collected less frequently, it would not be possible for CDC to carry out its commitments to protect the public health as mandated by these regulations.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This request fully complies with the regulation in 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

A8A. A **"60 Day Federal Register Notice"** was published in the Federal Register on October 21, 2020, Vol. 85, No. 204, Pages 66987-66988 (Attachment 2a). One comment was received regarding this notice (Attachment 2b). The commenter requested that the contact information for the biosafety officer field be mandatory. The commenter also requested that communications regarding the permit application be sent to the biosafety officer and permittee. CDC made no changes based on these comments as these recommendations did not request changes to the form but requested changes on how the program processes the application.

A8B. Consultation Outside the Agency

There has been no consultation outside the agency due to the delegation of responsibilities to the CDC as described herein.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payment or gift.

10. Assurance of Confidentiality Provided to Respondents

This submission has been reviewed by the Privacy Office which determined that the Privacy Act does apply. The information being collected to receive a permit as required under 42 CFR 71.54 includes the applicant's name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant's name, mailing address, phone numbers, and email address. To comply with the Office of Management and Budget (OMB) Memoranda (M) 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, the attached *Federal Register* notice was published on August 27, 2020 for the System of Record Notice entitled, ''Electronic Import Permit Program Portal (eIPP Portal)" (see Attachment 3).

The following special safeguards are provided to protect the records from inadvertent disclosure:

Authorized Users: Attempts to gain access by unauthorized individuals are automatically recorded and reviewed on a regular basis. Individuals who have daily access to these records are limited to DSAT staff who have responsibility for conducting regulatory oversight of the importation of infectious biological agents, infectious substances, and vectors of human disease into the United States.

Physical Safeguards: Paper records are maintained in locked cabinets in locked rooms in a restricted access location that is controlled by a cardkey system, and security guard service provides personnel screening of visitors. Electronic data files are password protected and stored in a restricted access location. The computer room is protected by an automatic sprinkler system, numerous automatic sensors (e.g., water, heat, smoke, etc.) are installed, and the appropriate portable fire extinguishers are located throughout the computer room. Computer workstations, lockable personal computers, and automated records are located in secured areas.

Procedural Safeguards: Protection for computerized records includes programmed verification of valid user identification code and password prior to logging on to the system; mandatory password changes, limited logins, virus protection, and user rights/file attribute restrictions. Password protection imposes username and password log-in requirements to prevent unauthorized access. Each username is assigned limited access rights to files and directories at varying levels to control file sharing. There are routine daily backup procedures and secure offsite storage is available for backup files.

Knowledge of individual tape passwords is required to access tapes, and access to the system is limited to users obtaining prior supervisory approval. To avoid inadvertent data disclosure, a special additional procedure is performed to ensure that all Privacy Act data are removed from computer tapes and/or other magnetic media. A backup copy of data is stored at an offsite location and a log kept of all changes to each file and all persons reviewing the file. Additional safeguards may also be built into the program by the system analyst as warranted by the sensitivity of the data set.

The DSAT and contractor employees who maintain records are instructed in specific procedures to protect the security of records, and are to check with the system manager prior to making disclosure of data. When individually identified data are being used in a room, admittance at either CDC or contractor sites is restricted to specifically authorized personnel.

Appropriate Privacy Act provisions are included in contracts and the CDC Project Director, contract officers, and project officers oversee compliance with these requirements. Upon completion of the contract, all data will be either returned to CDC or destroyed, as specified by the contract.

Implementation Guidelines: The safeguards outlined above are in accordance with the HHS Information Security Program Policy and FIPS Pub 200, `*Minimum Security Requirements for Federal Information and Information Systems*. Data maintained on CDC's Mainframe and the OPHPR Local Area Network (LAN) are in compliance with OMB Circular A-130, Appendix III.

Security is provided for information collection, processing, transmission, storage, and dissemination in general support systems and major applications.

The CDC will follow its established policies and procedures in releasing and/or withholding trade secret and/or confidential or financial information, in accordance with the Freedom of Information Act.

Privacy Impact Assessment Information

The following information is collected from the applicant to receive an import permit as required under 42 CFR 71.54. The information being collected to receive a permit as required under 42 CFR 71.54 includes the applicant’s name, mailing address, phone numbers, and email address. The information available on the permit includes the applicant’s name, mailing address, phone numbers, and email address.

The information is kept in a database which consists of permitted entities importing or subsequently transferring biological agents, infectious substances and vectors of human disease. This database is safeguarded; paper records are kept in locked files. Electronic data files are password protected and stored in a restricted access location. Only a small number of staff within DSAT has access to the information, and disclosure of information is stringently limited.

To comply with the Office of Management and Budget (OMB) Memoranda (M) 07-16, Safeguarding Against and Responding to the Breach of Personally Identifiable Information, the attached *Federal Register* notice was published on August 27, 2020 for the System of Record Notice entitled, ‘‘Electronic Import Permit Program Portal (eIPP Portal)” (see Attachment 3).

11. Institutional Review Board (IRB) and Justification for Sensitive Questions

This data collection does not include personal questions of a sensitive nature. Institutional Review Board approval is not required. These activities were determined to be public health non-research.

12. Estimates of Annualized Burden Hours and Costs

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (Attachment 4a) is used by laboratory facilities, such as those operated by government agencies, universities, and research institutions to request a permit for the importation of biological agents, infectious substances, or vectors of human disease. Based on information from eIPP, IPP receives approximately 2000 requests per year. The average burden per response is 20 minutes and the total estimated annualized burden is 667 hours.

The Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (Attachment 4a) is used based on the conditions indicated on import permit where a separate permit is required to transfer biological agents, infectious substances, or vectors of human disease from the importer to another facility in the United States. The IPP estimates an average of 380 transfers per year. The estimated burden per response is 10 minutes and the total estimated annualized burden is 63 hours.

The Application Requesting to Import Live Bats (Attachment 4b) is used by laboratory facilities such as those operated by government agencies, universities, research institutions, and for educational, exhibition, or scientific purposes to request a permit for the importation of bats. Based on information from eIPP, IPP receives three requests per year. It takes applicants 20 minutes to complete the application. The total estimated annualized burden is 1 hour.

The “Application for Permit to Import Infectious Human Remains into the United States” (Attachment 4c) is used by facilities that will bury/cremate the imported cadaver and educational facilities to request a permit for the importation and subsequent transfers throughout the U.S. of human remains or body parts that contains biological agents, infectious substances, or vectors of human disease. Based on information from eIPP, IPP receives approximately 100 requests per year. It takes the applicants 20 minutes to complete. The total estimated annualized burden is 33 hours.

The total estimated annualized burden for all information collection is 764 hours.

Table A12A. Estimate of Annualized Burden Hours

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Total Burden Hours
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (42 CFR 71.54)	2000	1	20/60	667
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (42 CFR 71.54) – SUBSEQUENT TRANSFERS	380	1	10/60	63
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats (42 CFR 71.54)	3	1	20/60	1
Applicants Requesting to Import Infectious Human Remains into the United States	Application for Permit to Import Infectious Human Remains into the United States (42 CFR 71.54)	100	1	20/60	33
Total					764

Table A12B. Estimate of Annualized Cost to Respondent

Type of Respondent	Form Name	No. of Respondents	No. Responses per Respondent	Average Burden per Response (in hours)	Avg.Hourly Wage	Total Cost
Applicants Requesting to Import	Application for Permit to Import	2000	1	20/60	$38.24	$25,493

Biological Agents, Infectious Substances and Vectors	Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (42 CFR 71.54)					
Applicants Requesting to Import Biological Agents, Infectious Substances and Vectors	Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States (42 CFR 71.54) – SUBSEQUENT TRANSFERS	380	1	10/60	$38.24	$ 2,422
Applicants Requesting to Import Live Bats	Application for a Permit to Import Live Bats (42 CFR 71.54)	3	1	20/60	$38.24	$ 38
Applicants Requesting to Import Infectious Human Remains into the United States	Application for Permit to Import Infectious Human Remains into the United States (42 CFR 71.54)	100	1	20/60	$38.24	$1275
Total						$ 29,228

When estimating the annualized burden costs, CDC assumes that the hourly burden would be evenly split between managerial staff and clerical staff. We are using an average hourly respondent labor rate of $59.56 for managerial staff and $ 16.92 for clerical staff. To calculate the mean hourly rate, we averaged these two figures for an hourly wage rate of $38.24. These rates were obtained from the Bureau of Labor Statistics, from the 2018 Occupational

Employment Statistics Survey by Occupation (http://www.bls.gov/oes/). The total estimated annualized burden cost is $29,228.

13. Estimates of Other Total Annual Cost Burden to Respondents or Record keepers

Respondents incur no capital or maintenance costs. The only costs incurred to respondents are those associated with telephone calls, mailing, and fax transmissions. All of these costs are part of normal business expenses.

14. Annualized Cost to the Government

The total estimated cost for implementing these regulatory activities for fiscal year 2020 is $1,333,495. This estimate includes 6 full-time Federal Employees (FTE) currently working in the import permit program. It also accounts for the program performing 23 inspections per year with two inspectors at a cost of $2000 per inspection. Additional costs incurred by the program are costs as shown below.

FY 2020 Annualized Government Cost

Personnel:	6 FTEs	$ 504,607
Import Permit Database:		$ 697,840
Travel:		$ 92,000
Equipment, supplies and materials:		$ 37,063
Administrative Costs:		$ 3,985
Total:		$ 1,335,495

15. Explanation for Program Changes or Adjustments

The changes are discussed below.

Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States

- Two minor changes to the form are proposed, but do not change the estimated burden per response.
    - We will remove question 10 “Will the permittee be the courier of the imported biological agent?” from Section A since it is the same question found in section C, question 1.
    - We will add an example to section F, question 2 for clarity to read, “Protective Clothing (e.g., laboratory coat).”
- There are no changes to the number of respondents, the estimated burden per response, or

total burden hours for this row of the burden table.

Form	Number of respondents	Frequency of Response	Average Burden per Response (in hours)	Total Response Burden (in hours)
Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States	2000	1	20/60	667

- The eIPP employs a modern user interface and applicants no longer need to consult guidance to complete the application form. We are eliminating this component of burden.

Form		Number of respondents	Frequency of Response	Average Burden per Response (in hours)	Total Response Burden (in hours)
Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States **Guidance**	Current Approval	2000	1	10/60	333
	Revision Request	0	0	0	0
	Net Change				-333

- Due to implementation of the more efficient eIPP, we are also reducing the estimated burden for Subsequent Transfers, which also utilize this form. The revised estimated burden per response changes from 50 minutes per response to 10 minutes per response.

Form		Number of respondents	Frequency of Response	Average Burden per Response (in hours)	Total Response Burden (in hours)
Application for Permit to Import Biological Agents, Infectious Substances and Vectors of Human Disease into the United States – **Subsequent Transfer**	Current Approval	380	1	50/60	317
	Revision Request	380	1	10/60	63
	Net Change				-254

<u>Application for a Permit to Import Live Bats</u>

Based on information from eIPP, we are reducing the estimated number of applicants from 10 per year to 3 per year. There is no change to the estimated burden per response.

Form		Number of respondents	Frequency of Response	Average Burden per Response (in hours)	Total Response Burden (in hours)

Application Requesting to Import Live Bats	Current Approval	10	1	20/60	3
	Revision Request	3	1	20/60	1
	Net Change				-2

- Finally, the improved eIPP allows us to eliminate burden that was previously associated with reviewing guidance for completing the Application for a Permit to Import Live Bats.

Form		Number of respondents	Frequency of Response	Average Burden per Response (in hours)	Total Response Burden (in hours)
Application for a Permit to Import Live Bats **Guidance**	Current Approval	10	1	10/60	2
	Revision Request	0	0	0	0
	Net Change				-2

Application for Permit to Import Infectious Human Remains into the United States

- There are no changes to form content, the number of respondents, the estimated burden per response, or total burden hours associated with this form.

Form	Number of respondents	Frequency of Response	Average Burden per Response (in hours)	Total Response Burden (in hours)
Application for Permit to Import Infectious Human Remains into the United States (42 CFR 71.54)	100	1	20/60	33

The total estimated annualized response burden will decrease from 1355 hours to 764 hours (-591 hours).

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication of this data. The data collection is used solely to carry out the provisions of the regulation.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

The display of the OMB expiration date is not inappropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.

List of Attachments:

Attachment 1a	Public Health Service Act (42 U.S.C. 264)
Attachment 1b	Foreign Quarantine; Import Regulations for Infectious Biological Agents, Infectious Substances, and Vectors (42 CFR 71.54)
Attachment 1c	42 CFR 71.55, Importation of Human Remains
Attachment 2a	60-Day Federal Register Notice
Attachment 2b	Public Comment
Attachment 3	System of Record Notice
Attachment 4a1	Application for Permit to Import Infectious Biological Agents (Infectious Substance and Vectors) of Human Disease into the United States – old form with tracked changes
Attachment 4a2	Application for Permit to Import Infectious Biological Agents (Infectious Substance and Vectors) of Human Disease into the United States – revised form
Attachment 4b	Application for Permit to Import or Transfer Live Bats
Attachment 4c	Application for Permit to Import Infectious Human Remains into the United States